

POLICY FOR THE TRANSFER OF MATERIALS FROM NIH INTRAMURAL LABORATORIES

1.0 INTRODUCTION

1.1 Unique research materials that arise from biomedical research are often essential resources to other researchers. As a valuable resource, these materials must be managed in a way that promotes their responsible and fair distribution. This policy document should be read as complementary to the guidance that can be found in the Guidelines for the Conduct of Research in the Intramural Research Programs at NIH (<http://www.nih.gov/science/irnews.htm>) and NIH Principles for Sharing Biomedical Research Resources, the “Research Tools Guidelines” (http://www.ott.nih.gov/policy/research_tool.aspx)

1.2 Certain categories of materials require special attention. This policy will focus on, but is not limited to, the use and distribution of human materials. NIH providers must abide by the highest scientific and ethical standards to preserve the public’s trust and the substantial investment these resources represent. NIH providers who transfer or distribute materials to non-NIH researchers, including collaborators and companies, must comply with strict NIH standards to ensure that these valuable resources are adequately protected.

1.3 This document explains the appropriate agreements and signatory authorities required for the transfer of materials from an NIH scientist acting in his or her NIH intramural capacity or for transferring materials from an NIH intramural laboratory for research purposes. This policy does not apply, however, to the transfer of human samples to a laboratory for testing on a fee for service basis or for any diagnostic purpose. Human subjects’ protections and Privacy Act requirements are applicable to materials under the control of all NIH staff, regardless of their primary assignments in intramural or extramural program areas or where the materials are physically stored.

1.4 Consistent with well established management practices, when transferring human materials requiring an additional NIH signatory beyond the laboratory chief or NIH provider, NIH providers may not sign in the capacity of both the NIH provider and the additional signatory. See Section 6 of this Policy for additional information on the type of agreements and signature authority required to transfer materials. **Because of the diverse nature of the kinds of samples that NIH scientists wish to send to other scientists outside of the NIH, and the complex nature of the oversight requirements, it is strongly recommended that a TDC be consulted to determine what paperwork is needed for most transfers.**

2.0 MODELS

2.1 As used herein, a Material Transfer Agreement (“MTA”) is a written document to facilitate the free transfer of materials between NIH scientists and other individuals or institutions (see Section 6.6 below for additional considerations in sending materials to for-profit institutions). For example, an MTA can be a model agreement such as the NIH Simple Letter Agreement (“SLA”), the Uniform Biological MTA (“UBMTA”), or one specifically developed for the transfer of materials from humans. While the use of an MTA or other appropriate agreement is preferred when exchanging materials, the NIH provider and recipient investigators may exchange a letter or memorandum designating the materials transferred and general intended use for. research not involving human materials or research with human subjects. An MTA or other appropriate agreement with necessary terms as described in section 6 must be used when transferring human materials or research with human subjects. While the recipient should not be charged a fee for the materials under an MTA, the shipping costs can be charged to the recipient.

2.2 When materials are transferred within the NIH, there is no requirement under this policy to use an MTA. However, an IC may require an MTA or other appropriate agreement when transferring or receiving material to or from another IC.

2.3 In general, when multiple signatures are required for the transfer of materials, one duly authorized institute official can sign the agreement while a secondary institute approval can be indicated on the agreement by initials or a stamp or other documentation of review and approval.

2.4 In this document, the term “collaboration” refers to research involving more than one laboratory where the exchange of materials and associated information rises to a level that warrants co-authorship on a publication of the results. Collaborations with academic or non-profit partners should normally be documented in Collaboration Agreements, Clinical Trial Agreements (“CTAs”) or modified MTAs. Collaborations with investigators at for-profit institutions should normally be documented in Cooperative Research and Development Agreements (“CRADAs”), CTAs, or Collaboration Agreements.

3.0 DISTRIBUTION

3.1 Model agreements can be found at <http://www.ott.nih.gov/index.aspx>. If TDCs add additional non-standard terms to agreements for the transfer of materials, such terms should be reviewed by the Office of General Counsel (“OGC”) and the Office of Technology Transfer (“OTT”) to the extent such terms have not been previously approved for a particular use or by OGC and the NIH Office of Human Subjects Research (“OHSR”) to the extent they raise issues concerning personal privacy or the protection of human subjects.

3.2 Materials should be distributed in a fair manner and without bias to qualified recipients. For materials that self-replicate or can be produced in large quantities, the NIH laboratory is usually able to provide the materials to essentially anyone who requests them. In such cases, NIH provider’s role is “ministerial”, i.e. there is no judgment to be made in providing the materials if the recipient is engaged in research at a recognized institution. Examples include bacterial or

yeast strains, cDNAs and monoclonal antibodies where the NIH provider can culture the hybridoma.

3.3 The issue of real or apparent distribution bias usually arises in the context of materials limited in quantity either because of expense or by their nature such that the NIH provider may have to prioritize the response to requests for the materials. In this case, the NIH provider should work with IC staff, such as the TDC, Ethics Officer, or Office of the Scientific Director, to develop a fair means of distributing materials that avoids bias or conflicts of interest. Examples of these materials include polyclonal antibodies, mouse strains where colony size is limited or chemical compounds where extraction procedures or synthesis result in low yields.

4.0 DEFINITIONS

4.1 For purposes of this policy, **“materials from humans” include those obtained directly from humans as well as derivatives of human materials.** Those obtained directly from humans include, but are not limited to, everything from tissue (e.g. bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, kidney), blood, gametes (e.g. sperm and ova), embryos, fetal tissue, and waste (e.g. urine, feces, sweat, hair and nail clippings, shed epithelial cells, placenta) as well as extracted or subcomponent parts of these materials including whole genomic DNA, plasma, protein fractions, or fractionated cells (adapted from Eiseman, E., Castillo, J., Handbook of Human Tissue Sources, RAND Monograph Report 7, 1999). The category **“derivatives of materials originally obtained from humans”** includes human cell lines, recombinant DNA clones of human genes, and isolated infectious agents from humans.

4.2 The following general definitions apply to the degree to which materials from humans are:

Unlinked: Materials that were initially collected with identifiers but, before research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. This does not preclude linkage with existing clinical, pathological, and demographic information so long as all subject identifiers are removed prior to distribution or receipt.

Coded: Materials that are unidentified for research purposes by use of a random or arbitrary alphanumeric code but that may still be linked to their sources through use of a key to the code available to the NIH provider or collaborator.

Identified: Materials that are still attached to a readily available subject identifier such as name, social security number, study number, hospital number, medical record number, address, telephone number, etc., such that the identities of the subjects can be ascertained.

See OHSR Sheet 14 entitled “NIH Requirements for the Research Use of Stored Human Specimens and Data” at <http://ohsr.od.nih.gov/info/sheet14.html>.

5.0 HUMAN SUBJECT AND PRIVACY ACT CONSIDERATIONS

5.1 Generally, NIH requires that human materials can be transferred only after IC Institutional Review Board (“IRB”) or OHSR review and approval. *See* OHSR Information Sheet 14, available on the OHSR website (and relevant successor guidance). The recipient must agree to conduct the research in accordance with the HHS rules for the protection of human subjects found at 45 C.F.R. Part 46, as applicable. Documentation should specify compliance with these regulations, the intended use of the materials, duration of intended use, and the plan for final disposition of unused materials.

5.2 In addition to the requirements of 5.1, if the materials and/or associated data are maintained in accordance with the Privacy Act in a System of Records, retrieved by a name or other identifier linked to the human subject, then an authorized NIH official must determine if identified or coded material with a key will be transferred and that: (a) provision of the data is for research purposes and does not violate legal or policy limitations under which the information was provided, collected or obtained; (b) the research purpose cannot be reasonably accomplished without provision of individual identifiable information; and (c) the research purpose warrants the risk to the privacy of the individual that additional exposure might bring. Moreover, the signed written agreement documenting the transfer must specify that the recipient agrees to limit access to personally identifiable information to only those individuals involved in the research project and only after they have been informed of, and agreed to, the provisions stated therein. Recipient must further agree to: (a) maintain any transferred personally identifiable information in a secure manner that restricts access to any individual not involved in the research project; (b) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project; and, (c) make no further use or disclosure of the information unless approved by NIH, except as required by law.

When identifiers or a code key are being transferred to a recipient, the MTA or other appropriate agreement must reference the Privacy Act of 1974, 5 U.S.C. § 552 as amended.

For information concerning the Privacy Act and the applicable System Of Records Notice, contact the IC Privacy Coordinator: http://oma.od.nih.gov/about/contact/browse.asp?fa_id=3.

6.0 CATEGORIES

6.1 **Materials that are not obtained from humans.** If these materials will not be used by the recipient in human research, the authorized signatory is the TDC or Lab Chief or higher depending on the IC delegation of authorities. One of the model MTAs may be used. If the materials will be used by the recipient in research in humans, a modified MTA or other appropriate agreement should be used requiring compliance with human subjects regulations at 45 C.F.R. Part 46. The authorized signatories are the TDC and the SD, Deputy SD or higher official within the IC. The TDC can provide assistance with the agreement. If the NIH provider is collaborating with the recipient, the NIH provider should first obtain NIH IRB or OHSR review/approval, as necessary.

6.2 Materials that are derivatives of materials originally obtained from humans and that are NOT identified, are unlinked, or are coded and NIH does not have access to the code. These materials are treated like those in section 6.1 above.

6.3 Materials that are derivatives of materials originally obtained from humans and that ARE identified or they are coded and NIH has access to the code. When derivative materials still retain identifiers, the materials are treated as identified materials from humans. An MTA or other appropriate agreement should be used with terms added to require the recipient's compliance with human subjects regulations at 45 C.F.R. Part 46, as applicable, and specification of the intended use, duration of use, and final disposition. If the materials will not be identified to the recipient investigator or, if coded but the code key will not be released, the agreement should specify that the NIH provider will not give the recipient access to identifiers and need not require the recipient's compliance with 45 C.F.R. Part 46. The NIH provider must also assure that the terms of the consent(s) under which the materials were obtained are not inconsistent with providing them to the recipient. For materials that will be identified or are identifiable because of access to the code by the recipient, the NIH provider must obtain NIH IRB or OHSR approval before release. In addition, an agreement as prescribed in section 5.2 is required if the materials/data are maintained in a Privacy Act System of Records, i.e., retrieval by name or unique identifier by the NIH. For materials that will not be identified to the recipient, the NIH provider must obtain NIH IRB approval when collaboration is anticipated. When no collaboration with the recipient investigator is anticipated, the NIH provider must obtain either IRB or OHSR approval as applicable. The authorized signatories for these agreements are the TDC and the IC Director, Deputy Director, SD, Deputy SD or Clinical Director.

6.4 Materials that are obtained directly from humans but are NOT identified, are unlinked or are coded and NIH does not have access to the code. An MTA or other appropriate agreement should be used with specification of the intended use, the duration of use, and final disposition. The NIH provider must obtain NIH IRB or OHSR approval before sending materials. The authorized signatories for these agreements are the TDC and the IC Director, Deputy Director, SD, Deputy SD or Clinical Director.

6.5 Materials that are obtained directly from humans and that ARE identified or they are coded and NIH has access to the code. The requirements for the transfer of these materials are the same as materials in section 6.3.

6.6 Additional considerations for materials that constitute an invention whether they are patented, patent pending or no patent is sought. Materials constitute an invention if they represent patentable subject matter, that is, they differ from a product of nature because they have been modified by human activity. Some examples include: a transgenic or knock-out mouse, a recombinant DNA expression vector, and an isolated and purified cell line but not a primary explant.

6.7 In addition to the policy requirements described above, the NIH OTT, in consultation with the IC TDC, will consider licensing materials that constitute an invention if the recipient is a for-profit institution or otherwise engaged in commercial development activities. If the TDC

recommends that the material be licensed, the TDC should send a request to OTT for negotiation of a royalty-bearing license agreement along with the Employee Invention Report (EIR) as described in PHS Technology Transfer Policy Manual Chapter 201. If the IC recommends sending the materials under an MTA rather than a license, the TDC should send such a request to OTT for review. TDCs may transfer materials constituting an invention without OTT approval if NIH has published a paper which would require access to the material to confirm its conclusions or if the transfer supports a research collaboration or NIH SBIR/STTR award, as long as the agreement governing the transfer limits the scope of use to confirmation of results, the NIH collaboration or SBIR/STTR award, as applicable. It is helpful to note in such agreements that further uses may require a license.

6.8 Additionally, if the transfer is part of a collaboration between an NIH scientist and a non-NIH scientist at a company, a CRADA may be the appropriate mechanism. The TDC should be consulted to develop and negotiate the agreement. TDCs submit CRADAs in final form to the NIH CRADA Subcommittee for review with the IC Director, Deputy Director, or SD serving as the IC authorized signatory.

7.0 Transportation and Handling of Materials

7.1 NIH's shipment of materials to qualified requestors, as well as NIH's receipt and use of materials originating elsewhere, will be in accordance with applicable laws, regulations, and policies. The nature of the materials (e.g., biological products, diagnostic specimens, infectious materials, etc.) will determine which regulations and policies are applicable.

7.2 Information can be found at:

NIH Policy Manual Chapter 1340-1 – Permits for Import or Export of Biological Material (<http://www1.od.nih.gov/oma/manualchapters/management/1340-1/>)

NIH Policy Manual Chapter 3035 – Working Safely with Hazardous Biological Materials (<http://www1.od.nih.gov/oma/manualchapters/intramural/3035/>)

7.3 When shipping and receiving materials, please refer to guidance on biological and chemical safety available from the Division of Occupational Safety and Health, NIH Office of Research Services (ORS): http://dohs.ors.od.nih.gov/shipping_biological_material_main.htm. This guidance includes:

- General Information on Shipping Biological Materials
- Training
- Shipping Biological Products
- Shipping Diagnostic Specimens
- Shipping Infectious Materials
- Shipping Radioactive Materials
- Resources for Shipping Biological Materials

For further information, consult the IC Safety and Health Specialist. A list of specialists is available at http://dohs.ors.od.nih.gov/safety_health_specialists.asp.

8.0 INCOMING MATERIALS

When an MTA or other agreement governing the transfer of materials into the NIH is offered by an outside provider to transfer materials, the NIH recipient should consult the TDC to review and approve any changes from the model MTAs and to provide signatures for the MTAs as may be required by the IC. In addition, if the materials were obtained directly from humans, constitute derivatives that are identified or coded or will be used in humans or human subjects research, the NIH recipient should consult with the IC IRB or OHSR to obtain the appropriate approval.

9.0 CONCLUSION

9.1 Generally, NIH providers planning to transfer human materials should contact their IC Technology Development Coordinator (TDC) (see http://www.ott.nih.gov/nih_staff/tdc.aspx), OHSR (<http://ohsr.od.nih.gov>) and/or their IC IRB, and their IC Privacy Act Coordinator or the NIH Privacy Act Officer for appropriate guidance. These offices should also be contacted when NIH recipients are planning to receive identified or coded human research materials from outside the NIH.

9.2 NIH providers and ICs are responsible for maintaining adequate records of determinations, materials transferred and the agreements used to transfer them (unless the requestor is referred to OTT for a license). Moreover, information about transfers of materials should be accessible by the TDC or stored in an NIH-wide data system, if available.

EFFECTIVE DATE: The administrative requirements announced in this Policy for the approval and use of agreements to document material transfers become effective 60 days after a model MTA for the transfer of human materials is approved and disseminated to the NIH TDCs. Before and after that date, however, all laws, regulations, and NIH policy for the protection of human research participants, and privacy, many of which are also described in this Policy, must be followed, as applicable.